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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,267	10/31/2001	Lakshmi Rambhatla	093/004P	1874

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EXAMINER	
TON, THAIAN N	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 04/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/001,267	**Applicant(s)** RAMBHATLA ET AL.	
	Examiner Thaian N. Ton	**Art Unit** 1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 March 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *13-40*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Joe Woitach
AU 1632

Continuation of 3. NOTE: The amendments to the claims raise new issues of search and/or consideration because the recitation of "an effective concentration" of a histone deacetylase inhibitor, and the production of at least about 40% of specific differentiated cells would require new considerations under 112, 1st and 102/103. .

Continuation of 11. does NOT place the application in condition for allowance because: The amendments to the claims are not entered. The prior rejections of record are maintained. The obviousness-type double patenting rejection is maintained. Applicants argue that the claims in the '589 patent cover a product, namely a set of cell populations, that the Office has applied a 2-way test of obviousness, where only a one-way test is permitted, and that the claims of the '589 patent do not suggest generating hepatocyte lineage cells using a histone deacetylase inhibitor. See p. 8 of the Response. This is not persuasive. As a one-way test, the instant claims are directed to methods that result in the cell populations of the '589 patent. Thus, given the claims of the instant application, the claims of the '589 patent are obvious, because the methods taught by the instant specification would only result in the cells claimed in the '589 patent.

Applicants further argue, that with regard to the enablement requirement in the prior Office action, that it is unnecessary for the claims to indicate the concentration of buytrate needed to effect differentiation into hepatocyte lineage cells. The specification exemplifies butryate concentrations that are effective, and should the reader deviate from the exemplified concentration, this can be done with undue experimentation. Furthermore, Applicants argue that the amendment reciting, "an effective concentration" of a histone deacetylase inhibitor overcomes the prior rejection. Finally, Applicants point to the specification to show that the working exmaples show that the process can be done using a number of histone deacetylase inhibitors. See pp. 8-9. This is not persuasive. Firstly, the amendments to the claims have not been entered, thus, the rejections of record are maintained. Secondly, it is noted that the claims require a certain percentage of cells to result in hepatocyte lineage cells (60%). The working examples in the specification provide specific examples using butyrate to produce these percentages. Table 3 provides the induction of hepatocyte phenotypes using the histone deacetylase inhibitors recited in Applicants' Response, but nowhere does this table provide sufficient guidance as to the molar amount of these inhibitors, or the percentage of cells produced. The mere recitation of a phenotype fails to enable the claims. Finally, it is maintained that the art recognizes that specific guidance must be provided to enable the claimed invention, because the concentration of a particular histone deactylase inhibitor is crucial in order to produce hepatocyte lineage cells, and thus, critical to practice the claimed invention. See also, pp. 5-6 of the Final Office action.